DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 11, 2015

Argon Med. Productions & Vertriebs Gesellschaft mbH & Co. KG
c/o Ms. Linda Saylor
Argon Medical USA, LLC
1000 Corporate Drive
Marshfield, WI 54449

Re: K141159
Trade/Device Name: K3Pro Konus Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 6, 2015
Received: February 9, 2015

Dear Ms. Saylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141159

Device Name
Konus Dental Implant System

Indications for Use *(Describe)*
The Konus K3Pro and K3Pro Rapid Implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Argon Medical Productions & Vertriebs Gesellschaft mbH & Co. KG

510(k) Summary

Date Submitted	January 15, 2014
Manufacturer and Address	Argon Medical Productions & Vertriebs Gesellschaft mbH & Co. KG Mainzer Street 346 Bingen am Rhein 55411
Manufacturer Contact	Richard Donaca CEO/Managing Director Tel: 011-49-6721-3096-0 Fax: 011-49-6721-3096-29
US Agent	Argon Medical USA LLC 1000 Corporate Dr. Marshfield, WI. 54449
US Agent Contact	Linda Saylor Regulatory Specialist Tel:715-387-2642 Fax:715-387-4100
Proposed Trade Name	K3Pro Konus Dental Implant System
Device Classification	Class II
Regulation	872.3640
Device Product Codes	DZE & NHA
Device Description	The K3Pro Konus Dental Implant System include endosseous Rapid and Sure root form and threaded, tapered and straight implants, they come in a range of diameter sizes 3.0 mm to 6.0 mm and range in length from 7.5 mm to 17 mm. Cover screws, healing caps, straight and angled dental implant abutments with threaded abutment connection having a Morse style taper. With a range of 0° to 30 ° angle. Abutment screws, temporary abutments, ball abutments, in a variety of diameters and heights to accommodate differing patient anatomy. The implants are manufactured from pure, implant-grade 4 titanium. The abutments are manufactured from Grade 5 Ti-6Al 4V-ELI. The internal connection has a 2 mm mini connection with a Konus connection with a 3° taper with a hexagonal orientation. The Standard has a 3 mm Konus connection with a 3° taper with a hexagonal orientation. Cover screws and healing caps provide protection to the threads of the abutment connection during endosseous and gingival healing. Cover screws are pre-packaged with each implant. Healing caps are provided as an alternative to the cover screw and are packaged separately.
Intended (Indications for) Use	The Konus K3Pro and K3Pro Rapid Implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.
Materials	The K3Pro Konus Dental Implants are manufactured from Pure Titanium Grade 4 and the abutments are manufactured from Titanium Grade 5 titanium alloy (Ti-6Al-4V ELI)
Predicate Devices	Bicon Implants (K092035) Implant-One (K102822) Friadent (K073075) NobelActive 3.0 (K102436) BioDenta Dental Implant System Bone Level Tapered (K133884)

Substantial Equivalence and Technological Characteristics: The fundamental scientific technology of the K3Pro Konus Dental Implant System is the same as the previously cleared devices as shown below in appendix table A.

Appendix Table A

System:	K3Pro	Bicon Implants	Implant-One	Friadent	NobelActive 3.0	BioDenta Dental Implant System Bone Level Tapered
Material of Manufacture	Grade 4 Ti Grade 5 Ti-6Al 4V-ELI	Grade 5 Ti6A14V	Titanium and/or titanium alloy			
510k (number)	New Device	K092035	K102822	K073075	K102436	K133884
Endosseous implant	Root-form, Straight and Tapered	Tapered	Root-form, Tapered	Root-form, Straight and tapered	Root-form, Straight and tapered	Root-form, tapered
Method of stabilization	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation
Range of Diameters	3.0 – 6.0mm	3.0 –6.0 mm	3.25 - 5.5mm	3.0 –6.5mm	3.3 -6mm	3.0 – 6.0 mm
Range of Lengths	7.5-17mm	5.0 – 11 mm	8-14mm	8-17mm	8-16mm	6.5 – 14 mm
Modified surface	Yes, acid etched	Blasted and acid etched, or hydroxylaptite treated	Yes, AI02 blasted	Yes, acid etched	Yes, microtextured or HA coated	Yes, Spark Anodization
Connection to abutment	Hex alignment, 1.5° locking conical taper, screw attachment	1.5° Locking conical taper connection	Hex alignment, 6° included taper, screw attachment	Hex alignment, screw attachment	Hex alignment, 1° taper, screw attachment	Internal Hexagon 6° taper,
Abutments	Standard, Angled, Ball, Gold coping	Standard, Angled, Non Shouldered	Standard, Ball, Gold coping	Standard, Ball, Gold coping	Standard, Angled, Ball, Gold coping	Ti Alloy (Ti 6A1 4V)

Non-Clinical Testing: Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance fatigue testing in accordance with the FDA Guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments and ISO 14801 Dentistry Implants Dynamic Fatigue Test for Endosseous Dental Implants. The fatigue testing conducted indicates that the

device is strong enough to withstand the anticipated forces. The data included in the Appendix table A above demonstrate the substantial equivalence to the predicate devices listed.

A series of performance tests were conducted to demonstrate that the K3Pro Konus Dental Implant System does not raise any new issues of safety and efficacy. These tests include: fatigue, corrosion resistance and biocompatibility. The testing was done in accordance with ISO 14801 Dentistry Implants Dynamic Fatigue Test for Endosseous Dental Implants Second Edition 11/15/2007 and the FDA Guidance Class II Special Controls Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

No "Non-Pyrogenic" marketing claims are being made for any of the devices in the K3Pro System.

"The Konus Dental Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Konus Dental Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury."

Clinical Testing: Non-Clinical test data was used to support the decision of substantial equivalence. The subject device is substantially equivalent or exactly the same to the devices listed above in materials, range of diameters, and method of stabilization.

Conclusion: The subject device and the predicated devices have the same intended use, have similar technological characteristics, and are made of similar if not identical materials. The subject device and predicate devices encompass a very similar or the exact same range of physical dimensions, including diameter and length of the implants and diameter, height and angle of the abutments and a comparative surface area.